



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 29 1999

Re: Bapten®
Docket No. 98E-0854

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,485,088 filed by Alaco, Inc. under 35 U.S.C. § 156. The animal drug product claimed by the patent is Bapten® (beta-aminopropionitrile fumarate), which was assigned new animal drug Application (NADA) No. 141-107.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The NADA was approved on June 10, 1998, which makes the submission of the patent term extension application on August 10, 1998, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Austin R. Miller, Esquire
Schnader, Harrison, Segal & Lewis
Suite 3600
1600 Market Street
Philadelphia, PA 19103-7286

98E-0854

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

2002 '99 APR 30 P1:29
Memorandum

Date: APR 29 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for **Bapten**[®]

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned animal drug product under the Docket Number **98E-0854** stating that this particular patent is eligible for regulatory review.. The Patent Number is **4,485,088**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.